K102226

JAN - 4 2011

Section 5 - 510(k) Summary

This document is provided in the following pages.

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Sponsor Information:
Atom Medical Corporation
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Date Summary Prepared: July 30, 2010

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Device Name:
Trade Name(s): Dual Incu *i* (Atom Infant Incubator Model 100)
Classification Name: Neonatal Incubator
Classification Regulation: 880.5400
Panel: General Hospital
Product Code: FMZ

Predicate Device Information:
Device Name: V-2200 Infant Incubator
510(k) Reference: K061856
Manufacturer: Atom Medical Corporation

Device Name: Ohmeda Medical Giraffe Omnibed
510(k) Reference: K071175
Manufacturer: GE HEALTHCARE

Device Description:
Dual Incu *i* (Atom Infant Incubator Model 100) is a combination of an infant incubator and an infant warmer. This device consists of hood, a main body, a control panel and a warming heater (radiant warmer) and a stand with casters. A hood consists of a canopy and access doors (snap-open access port). An Oxygen sensor, a humidity sensor and a temperature sensor which monitor the air conditions inside the hood, are connected to the sensor module. A main body consists of a mattress, a mattress platform, a conditioning chamber, a humidity chamber. A control panel and skin temperature sensors are connected to the main body.

This device has a function that elevates the canopy. The device operates as an incubator when the canopy is closed, and the device operates as a radiant warmer when the canopy is opened.
This product has 2 types of function modes; one is "servo control mode" (called as "skin temperature control mode" also) and another is "manual control mode".

When the device is operated as an incubator, skin temperature can be set from 34° to 38° (including override) in "servo control mode", and air temperature inside the hood can be set from 23° to 39° (including override) in "manual control mode".
When the device is operated as an infant warmer, skin temperature can be set from 34° to 38° (including override) also in "servo control mode", and heater output of the warming heater can be set from 0 to 100%(in 5% increments) in "manual control mode".
In "servo control mode", baby's skin temperature is monitored by temperature sensor attached on baby's body, and baby's skin temperature is controlled according to difference between monitored baby's skin temperature and set skin temperature.
In "manual control mode", air temperature inside the hood is monitored by temperature sensor of sensor module, and air temperature inside the hood is controlled according to difference between monitored air temperature inside the hood and set air temperature, when the device is operated as an incubator.

The mattress platform can be tilted. X-ray cassette tray is installed under the mattress platform.
The device has 6 kinds of accessories; "Skin temperature sensor", "Oxygen sensor", "Piping hose for oxygen", "Electrostatics air filter", "Access port cover" and "Oxygen calibration tool", and these 6 accessories are available separately as replacements.

"SpO2 Module", "Oxygen Controller", "Weight Monitor" and "Humidifier Chamber" are components of this device, and it is optional whether they are initial attached initially or not.

If they are not attached initially, they can be attached later, and then SpO2/pulse monitoring, oxygen density controlling, weight monitoring and humidifying function can be available.
The 4 kinds of components can be supplied individually.
The stand can go up and down.

Intended Use:
The Dual Incu i is a combination of an infant incubator and an infant warmer. The device can transition from one mode to the other on user's demand.
The Dual Incu *i* is an incubator for newborns and premature neonates. It is mainly intended for temperature control in neonatal hypothermia, observation and examination in newborn nurseries, prevention of body temperature drop shortly after delivery, and pre-operative and post-operative intensive care in neonatal surgery. This incubator is provided with a function to control the infant's skin temperature. Optional functions include pulse oximetry and oxygen density controlling.

Comparison to Predicate Device:
Dual Incu *i* is a device that added the functions and specifications of the 510(k)-cleared Giraffe Omnibed to the 510(k)-cleared existing device Atom V-2200.

Main differences between Dual Incu *i* and Atom V-2200 are as follows.

1. The canopy of Dual Incu *i* can be electrically elevated. This function has been installed in the Giraffe Omnibed but has not been installed in the Atom V-2200.
2. At the time of opening of canopy (Opening mode), infrared light of Atom 100 is radiated and infant is warmed. This function has been installed in the Giraffe Omnibed but has not been installed in the Atom V-2200.

Dual Incu *i* is same combination of an infant incubator and an infant warmer as the Giraffe OmniBed. The technological characteristics of the Dual incu *i* as compared to the predicate products, the Atom V-2200 and the Giraffe OmniBed, are equivalent in the following areas and do not compromise the safety or efficacy of the device.

-Intended use
- Feature
- Appearance
- Temperature Modes
- Components and those function

Testing and Conclusions:

Dual Incu *i* is electrical medical device. Therefore, tests based on IEC60601-1, IEC60601-1-2, IEC60601-2-19 and IEC60601-2-21 standards were carried out for Dual Incu *i*, and it was verified that Dual Incu *i* is met to requirements of IEC60601-1, IEC60601-1-2, IEC60601-2-19 and IEC60601-2-21.

Biocompatibility was evaluated based on ISO10993-1. Infants-contacting parts of the Dual Incu *i* are not unprecedented and are generally used for various type of medical devices. And also, the materials are identical to those used for the 510(k)-cleared predicate device. Thus the biological safety can be evaluated to have been assured.

Validation has been conducted on the device software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JAN - 4 2011

Re: K102226
Trade/Device Name: Dual Incu i (ATOM Infant Incubator 100)
Regulation Number: 21 CFR 880.5400
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FMZ
Dated: December 21, 2010
Received: December 22, 2010

Dear Mr. Sugino:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

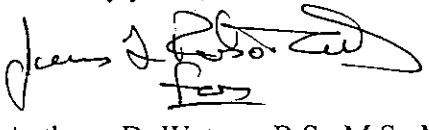
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102226

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Prescription Use ___XX____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K102226